

GP1642

PATENT
242/024
(DIV 1 OF '682)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Neil H. Bander

Serial No.: Not yet assigned

Filing Date: Herewith

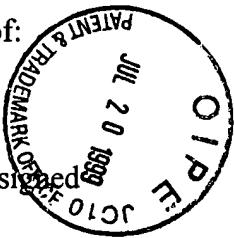
(Divisional of Serial No. 08/838,682

Filed on April 9, 1997

**For: TREATMENT AND DIAGNOSIS
OF PROSTATE CANCER**

Group Art: 1642

Examiner: Y. Eyler



JC618 U.S. PRO
09/357704
07/20/99



**PETITION TO MAKE SPECIAL UNDER 37 C.F.R. §1.102
BASED ON RELATION TO CANCER**

Assistant Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Applicant hereby petitions, pursuant to 37 C.F.R. § 1.102 and M.P.E.P. § 708.02, to make the above-identified application special and thereby advance examination of the application, due to the relation of the application to cancer.

07/29/1999 BALEXAND 00000049 122475 09357704

02 FC:122 130.00 CH

**CERTIFICATE OF MAILING
(37 C.F.R. §1.10)**

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as 'Express Mail Post Office To Addressee' in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

EL199138756US
Express Mail Label No.

July 20, 1999
Date of Deposit

Felicia Reyes
Name of Person Mailing Paper
Felicia Reyes
Signature of Person Mailing Paper

LA-100080.1

The invention relates to methods for the treatment and diagnosis of prostate cancer with biological agents, including antibodies or binding portions thereof. Prostate cancer is the most common cancer in men, and is the second leading cause of death in men who die from neoplasia. (Specification, page 1, lines 16-21.) Current methods for the detection and treatment of prostate cancer suffer from significant deficiencies. (Specification, page 1, line 24 to page 4, line 30.) Specifically, with respect to prostate cancer detection, imaging methods, such as computed tomography or magnetic resonance, are unable to detect tumors having a volume below about 1 cm. Furthermore, these methods are non-specific in that they are unable to specifically identify imaged masses as tumors. Other conventional methods rely on the detection of elevated levels of serum acid phosphatase. However, these methods also are non-specific and subject to false positive readings, due to the presence of phosphatase isoenzymes that are not correlated with disease.

With respect to methods to treat prostate cancer, current methods include surgical intervention and radio- or chemotherapy. (Specification, page 4, line 33 to page 6, line 27.) However, surgical intervention often does not guarantee removal of all cancerous cells, and prostate cancer has proven to be resistant to chemotherapy. Radiation therapy has significant side effects, and requires supplementation with hormones and other drugs that themselves induce side effects.

Current methods to detect and/or treat prostate cancer using monoclonal antibodies have met with limited success. Some antibodies cannot distinguish between normal and cancerous prostate cells. (Specification, page 7, line 26 to page 8, line 2.) As a result, detection and treatment are non-specific. Other antibodies are specific to malignant prostatic tissue, but can

only detect dead cancerous cells. (Specification, page 8, line 34 to page 9, line 21.) As a result, living, viable cancer cells cannot be detected or treated.

The present invention relates to methods for detecting and treating prostate cancer, using biological agents, including antibodies, directed against the extracellular domain of prostate-specific membrane antigen ("PSMA"). The biological agents and antibody recognize antigens which are exposed on the surface of living prostate epithelial cells, including cancerous prostate epithelial cells. (Specification, page 11, line 21 to page 12, line 2.) As a result, living cancerous epithelial prostate cells can be targeted by the binding agents and antibody of the present invention for detection and killing or ablation of the cancerous cells. The specification describes methods to accomplish such detection and killing or ablation. (Specification, page 13, line 9 to page 17, line 4.)

The claims now pending specifically point out and claim the use of biological agents, including antibodies, directed against the extracellular domain of PSMA in the detection and/or treatment of cancer. See Claims 1-19 and new Claim 80. The relationship of the application to cancer is thus indisputable.

The appropriate filing fee of \$130.00, as per 37 C.F.R. §1.17(i), is included herewith.

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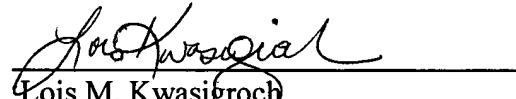
No additional fee is believed due at this time. The Examiner is authorized to charge any additional fee due or refund any overpayment to **Deposit Account No. 12-2475**. If a telephone conference would, in any way, facilitate prosecution of the application, the Examiner is encouraged to contact the undersigned.

Respectfully submitted,

LYON & LYON LLP

Dated: July 20, 1999

By:


Lois M. Kwasigroch
Reg. No. 35,579
Attorneys for Applicants

633 West Fifth Street, Suite 4700
Los Angeles, California 90071-2066
(213) 489-1600

PATENT
242/024
(DIV 1 OF '682)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:)
Neil H. Bander) Group Art Unit: 1642
Serial No.: Not yet assigned)
Filing Date: Herewith)
(Divisional of Serial No. 08/838,682)
Filed on April 9, 1997)
For: TREATMENT AND DIAGNOSIS OF)
PROSTATE CANCER)

STATEMENT OF LOIS M. KWASIGROCH

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I hereby certify, as applicant's undersigned attorney, that the deposits listed on page 30 of the present application and having ATCC Designation Nos. HB-12101 ("E99"); HB-12109 ("J415"); and HB-12127 ("J533") and HB-12126 ("J591"), were made pursuant to the Budapest Treaty on May 2, 1996, May 30, 1996, and June 6, 1996, respectively, and that all restrictions imposed by the depositor on the availability to the public of the deposited materials will be irrevocably removed as of the issue date of the above-identified patent application as a patent,

CERTIFICATE OF MAILING
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July 20, 1999
Date of Deposit

Felicia Reyes
Name of Person Mailing Paper
Felicia Reyes
Signature of Person Mailing Paper

PATENT
242/024
(DIV 1 OF '682)

and that the deposits will be replaced if viable samples cannot be dispensed by the depository.

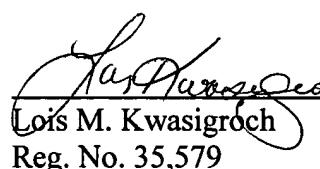
Copies of the ATCC deposit receipts are attached.

Respectfully submitted,

LYON & LYON LLP

Dated: 7/20/99

By:


Lois M. Kwasigroch
Reg. No. 35,579

633 West Fifth Street, Suite 4700
Los Angeles, California 90071-2066
(213) 489-1600



American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 898-055 ATCCNORTH • FAX: 301-770-2587

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Laboratory of Urological Oncology
Attn: Neil H. Bander, M.D.
Cornell Medical Center - Box 23
1300 York Avenue
New York, NY 10021

Deposited on Behalf of: Cornell University (c/o Dr. Neil H. Bander)

Identification Reference by Depositor: ATCC Designation

Mouse hybridoma Prost E99 HB-12101

The deposits were accompanied by: a scientific description a proposed taxonomic description indicated above.

The deposits were received by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested May 7, 1996. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Halley

Barbara M. Halley, Administrator, Patent Depository

Date: May 8, 1996

cc: Michael L. Goldman
Lauren S. Stich



AMERICAN TYPE CULTURE COLLECTION
12301 Parklawn Drive
Rockville, MD 20852 USA

Telephone: 301-881-2600

FACSIMILE

Date: May 7, 1998

To: Dr. Neil Bander
Laboratory of Urological Oncology
Cornell Medical Center - Box 23

City & Country: New York, NY

Fax Number: 1-212-746-8941

Total number of pages including this page: One (1)

From: ATCC Patent Depository

ATCC Patent Depository Fax Number: 301-816-4388

Reference: Patent deposit. Mouse Hybridoma Prost E99 assigned ATCC HB-12101. Date of deposit May 2, 1998. Paperwork will be forwarded to you in a few days.

As instructed, an invoice will be sent under separate cover to the Cornell Research Foundation, Ithaca, NY, as follows:

One time fee - 30 years	\$ 600.00
Informing of Requesters	360.00
Viability test	100.00
Phone/FAX charge	<u>10.00</u>
Total due ATCC HB-12101	\$1,070.00

[Handwritten signature]
PLEASE NOTE: The form you have used for this deposit is outdated. Bobbie Brandon retired from the ATCC two years ago. I will be sending you an updated form with your certificate. PLEASE DESTROY ALL OF YOUR OLD FORMS. Thanks.

Barbara Hailey
Barbara Hailey - Administrator, Patent Depository
Tel. (301)231-5519

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Docket 242/024
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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Cornell Medical Center
Attn: Dr. Neil H. Bander or Ms. Lauren Stich
Department of Urology
525 East 68 Street (Box 23, Rm. E-300)
New York, NY 10021

Deposited on Behalf of: Cornell Medical Center

Identification Reference by Depositor: ATCC Designation

Mouse hybridoma prost J415 HB-12109

The deposit was accompanied by: a scientific description a proposed taxonomic description indicated above.

The deposit was received May 30, 1996 by this International Depository Authority and has been accepted.

AT YOUR REQUEST: We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested June 5, 1996. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Bailey
Barbara M. Bailey, Administrator, Patent Depository

Date: June 5, 1996

cc: ✓ Michael L. Goldman
H. Walter Haessler



American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301) 231-5520 Telex: 908-764 ATCCROVE • FAX: 301-816-4366

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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3 AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

New York Hospital-Cornell Medical Center
Attn: Neil H. Bander, M.D.
Laboratory of Urological Oncology, Rm. E-300 (Box 23)
525 E. 68 Street
New York, NY 10021

Deposited on Behalf of: Dr. Neil H. Bander, Department of Urology, Cornell Medical Center

Identification Reference by Depositor:

ATCC Designation

Mouse hybridoma Prost J591	HB-12126
Mouse hybridoma Prost J533	HB-12127

The deposits were accompanied by: a scientific description a proposed taxonomic description indicated above.

The deposits were received June 6, 1996 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains, and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strains.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years from date of deposit, or five years after the most recent request for a sample, whichever is longer. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested June 12, 1996. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Barbara M. Hailey
Barbara M. Hailey, Administrator, Patent Depository

Date: June 13, 1996

cc: ✓ Michael L. G. Idman
H. Walter Haeussler